

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
15 April 2004 (15.04.2004)

PCT

(10) International Publication Number
WO 2004/030510 A3

(51) International Patent Classification⁷: **A61M 16/00**,
A62B 18/00, 17/04

(21) International Application Number:
PCT/IL2003/000798

(22) International Filing Date: 3 October 2003 (03.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/415,465 3 October 2002 (03.10.2002) US

(71) Applicant (for all designated States except US): IN-
SPURE [IL/IL]; 11a Sinai Ave., 34331 Haifa (IL).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **GAVRIELY, Oren**
[IL/IL]; 116A Moriah Avenue, 34618 Haifa (IL).

(74) Agent: **TSIVION, Yoram**; P.O.Box 1307, 37111 Pardes
Hanna (IL).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE,
GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,
MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,
RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

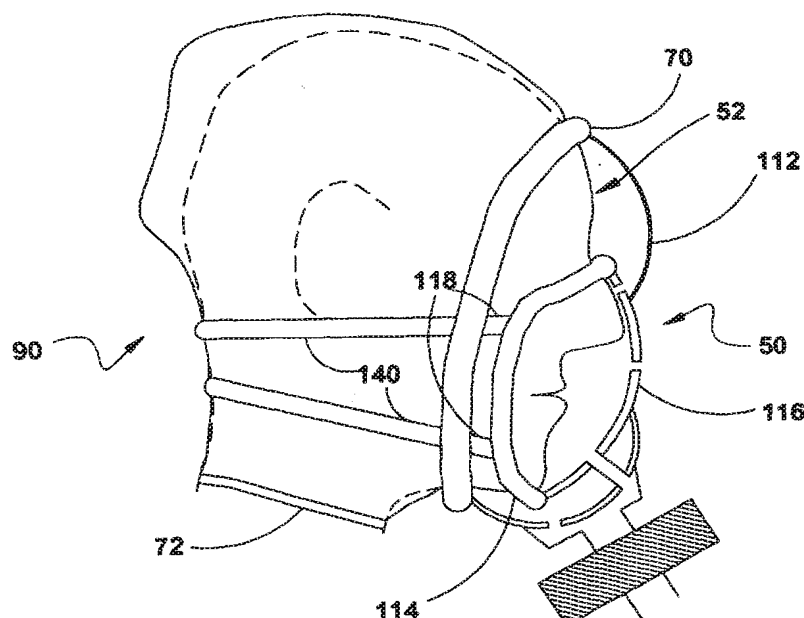
Published:

— with international search report
— before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
21 May 2004

[Continued on next page]

(54) Title: **DEVICE FOR PROVIDING PROTECTION TO THE RESPIRATORY SYSTEM**



(57) Abstract: A device for providing purified atmospheric air to a user. Air passes passively through a filter (46) and partitions into a mouse - nose compartment (50) and a face compartment (52). The air from the face compartment flushes a visor (112) and subsequently passes into the mouse - nose compartment. A hood compartment (54) sealed at the neck region is kept sealed off the face compartment from which it is sealed. Unidirectional valves (64) maintain the directional flow of air, and seal elements provide partition of compartments.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL03/00798

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61M 16/00; A62B 18/00; A62B 17/04 US CL : 128/201.25,206.12,206.17,206.24 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 128/201.25,206.12,206.17,206.24 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,340,024 B1 (BROOKMAN et al) 22 January 2002 (22.01.2002), see entire document.	1-5
X	US 6,328,031 B1 (TISCHER et al) 11 December 2001 (11.12.2001), see entire document.	1-5
X	US 5,431,156 A (SUNDSTROM) 11 July 1995 (11.07.1995), see entire document.	1-5
X	US 5,078,130 A (VAN OOSTEN et al) 07 January 1992 (07.01.1992), see entire document.	1-5
X	US 4,886,056 A (SIMPSON) 12 December 1989 (12.12.1989), see entire document.	1-5
X	US 4,807,614 A (VAN DER SMISSEN et al) 28 February 1989 (28.02.1989), see entire document.	1-5
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 11 March 2004 (11.03.2004)		Date of mailing of the international search report 13 APR 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230		Authorized officer Henry Bennett <i>J. Hurley</i> Telephone No. 703-308-0858

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
15 April 2004 (15.04.2004)

PCT

(10) International Publication Number
WO 2004/030510 A2

- (51) International Patent Classification⁷: **A61B**
- (21) International Application Number:
PCT/IL2003/000798
- (22) International Filing Date: 3 October 2003 (03.10.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/415,465 3 October 2002 (03.10.2002) US
- (71) Applicant (for all designated States except US): IN-
SPURE [IL/IL]; 11a Sinai Ave., 34331 Haifa (IL).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): **GAVRIELY, Oren**
[IL/IL]; 116A Moriah Avenue, 34618 Haifa (IL).
- (74) Agent: **TSIVION, Yoram**; P.O.Box 1307, 37111 Pardes
Hanna (IL).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

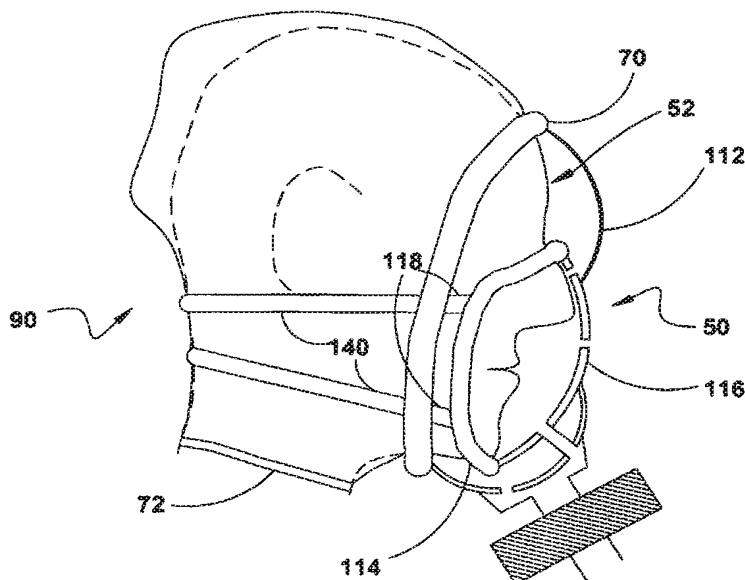
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **DEVICE FOR PROVIDING PROTECTION TO THE RESPIRATORY SYSTEM**



(57) Abstract: A device for providing purified atmospheric air to a user. Air passes passively through a filter and partitions into a mouse - nose compartment and a face compartment. The air from the face compartment flushes a visor and subsequently passes into the mouse - nose compartment. A hood compartment sealed at the neck region and also around the face compartment. Unidirectional valves maintain the directional flow of air, and seal elements provide partitioning into compartments.

WO 2004/030510 A2

DEVICE FOR PROVIDING PROTECTION TO THE RESPIRATORY SYSTEM

TECHNOLOGICAL FIELD OF THE INVENTION

The present invention deals with the protection of the respiratory system against harmful airborne agents. More specifically a device of the invention is worn as a face mask used against industrial, environmental and military airborne hazardous agents.

BACKGROUND OF THE INVENTION

Since the first world war the threat of poisonous airborne agents has become a public concern. Further awareness regarding health hazards borne by the air is currently on the rise because of the general environmental conditions and occasional disasters caused by industrial exposures and accidental leaks.

Airborne hazardous agents are either true gasses or aerosols, containing noxious molecules or microorganisms. They penetrate the human body chiefly via the respiratory tract. The exposure of the upper and lower airways and the lung alveoli to toxic gases cause severe local and systemic reactions that rapidly lead to incapacitation and death. To prevent exposure of the lungs to toxic gases and biological agents, a variety of protective gear and barriers have been developed. In principle these devices include an impermeable shield around the face, the head, or the whole body, and means of supplying fresh and decontaminated air to sustain pulmonary gas exchange. The protective gear that is currently available may be subdivided into two primary classes: passive and active.

Passive protection refers to gas masks where the flow of air into the mask

Passive protection refers to gas masks where the flow of air into the mask through the filter is driven by the kinetic energy provided by the user's own inspiratory system. Active protection refers to masks and other shields where the flow into the breathing circuit is driven by a pump or a blower.

5 Active protection has the distinct advantages of being more effective by preventing penetration of the toxic gases through cracks or incomplete seal between the mask and the skin. This is achieved by running excess flow into the breathing circuit and maintaining positive pressure inside the shield at all times. Active protection gear is also safer since it assures, at all times, ample

10 supply of fresh air, free of carbon dioxide and rich in oxygen. Additional advantage of active gear is the avoidance of excessive negative pressures needed to generate flow through the filter, especially during strenuous activity, when peak inspiratory flow is elevated.

The disadvantages of active protective gear are their higher cost, their

15 reliance on a power source such as batteries, their increased weight, their susceptibility to breakage and malfunction and their complexity. Of particular concern are the durability and shelf life of the batteries. The invention disclosed herewith is of a gas mask that is primarily of the passive type.

Additional classification of protective gear relates to the location of the

20 seal in relation to the user's skin. There are four types of mask seals: 1) the face mask, sealed around the user's face; 2) the mouth - nose mask, sealed only around the respiratory inlets; 3) the hood protective gear that is sealed around the neck; and 4) the hybrid double seal device that is constructed from an external hood or face mask and an inner mouth - nose compartment that

25 is sealed around the mouth and nose.

The face type gas mask is the standard model used by the military, such as the M40 used by the US army. It covers the mouth, nose and eyes and has a relatively large dead space. The seal of this mask is around the face from the forehead around the maxillae and cheeks down to below the

30 chin.

This seal of the facemask must fit snugly to prevent leakage of toxic gases into the mask. This seal is not applicable in specific cases. For

example beard wearers, or individuals with unusual facial proportions or deformations. In addition, the facemask requires individual sizing and meticulous adjustment of the pull-straps that hold the mask to the face. A common variant of the facemask, such as disclosed by Grove, Chase and Fritch in US pat. Number 6,176,239, includes an additional mouth - nose compartment inside the face mask. This compartment is also intended to fit snugly around the nose and mouth to reduce re-breathing of carbon dioxide and fogging of the mask lenses.

The mouth – nose mask only protects the user's respiratory inlet and requires separate goggles to protect the eyes. As such, it is not suitable for general protection against chemical and biological warfare, but is often used in industry where light weight and convenience are important and the level of exposure risk is well-known in advance.

The third type is the hood protection gear that is sealed around the user's neck. This hood can only be used as an active mask because of its large dead space and compliant walls that promote carbon dioxide retention if a pump or blower is not used.

The fourth type is the hybrid double seal device. Such a mask includes a mouth – nose compartment that fits the user's face snugly and an enclosing hood fitted with a visor and a membrane sealing it around the user's neck. This type of gear provides a high protection ratio, but is only safe to use if the mouth - nose compartment is tightly sealed. If the seal is incomplete or breaks as a result of head motion, speech or other movements, carbon dioxide-rich exhaled gas escapes into the hood cavity and is re-breathed during the subsequent inhalation. Such re-breathing may cause carbon dioxide build-up and suffocation.

Further classification of gas masks relates to the different user grouping. In essence, there are two subgroups: 1) masks intended for active personnel such as emergency crews and military personnel and 2) masks intended for sedentary civilian population. There are differences in design and construction as well as in distribution strategy for the two subgroups. The masks for civilian population are usually distributed with only rough individual

customization (ie., 'large', 'medium', 'small'). They must be very simple to use with only minimal training (eg., a video tutoring film). Moreover, the system must be both effective and safe beyond doubt for the vast majority of people. Thus, it should provide adequate protection while being safe under multitude
5 of circumstances. Safety criteria include upper threshold for inhaled carbon dioxide level ($F_{I}CO_2$) that must be less than 2% and a minimum value of inhaled oxygen ($F_{I}O_2$) that must be greater than 17%. These thresholds must not be violated for a period that is continuously longer than sixty seconds. The novel chemical-biological protection gear disclosed herewith is
10 specifically intended for use by such untrained, diverse civilian populations.

The final subdivision of protective gear is by the placement and configuration of the inlet and outlet respiratory valves. In all gas masks the exhalation outlet forms a direct communication with the mouth - nose compartment so that the exhaled gas can exit the system easily and promptly.

15 The placement of the inhalation valve(s) varies among gas masks, but in most systems including an inner mouth - nose compartment, there are two sets of inspiratory valves: 1) a valve leading from the filter into the cavity of the outer shell and 2) a valve or valves leading from the outer shell into the mouth - nose compartment. The advantage of this configuration is that fresh
20 air flushes the interior of the outer shell with every breath. This is most useful in keeping moisture from condensing on the lenses or visor elements of the mask. The disadvantage of this arrangement is that exhaled gas that may escape under the seal from the mouth - nose compartment into the shell mixes with the fresh gas and causes partial re-breathing of a carbon dioxide-
25 rich and oxygen-poor gas.

Placement of the inhalation valve directly in communication with the mouth-nose compartment is found in industrial mouth - nose masks where independent goggles are used for eye protection. When used in a facemask variant that does not have a sealed mouth - nose compartment, the internal
30 volume becomes too large (i.e., 500ml.) creating an excessive respiratory dead space, which may be too large for persons with small lung capacity.

DESCRIPTION OF THE DRAWINGS

5 Fig.1 is a block diagram describing the flow of air between compartments of a device of the invention;

Fig. 2 is is a block diagram describing the barring components of flow of air between compartments of a device of the invention;

10 Fig. 3 is a side view and partial cross section of the gas mask of the invention worn by a user;

Fig. 4 is a side view and partial cross section of a front portion of the gas mask of the invention worn by a user;

Fig. 5 is a is a side view and partial cross section of a front portion of the gas mask of the invention worn by a user showing air flow directions;

DETAILED DESCRIPTION OF THE INVENTION

The novel protection system described hereinbelow is a passive masking device for isolating the respiratory system of a user from airborne gases and or aerosols. It is constructed of three compartments, a hood which is sealed around the neck, a facemask sealed around the face and a mouth - nose chamber sealed around the respiratory inlet.

Fig. 1 is a block diagram describing schematically the airflow channels in a protective device embodying the present invention. The atmospheric air **40** comes in contact with the wearer of the device of the invention, through either of two paths or both. In path **42** the air passes through a filter before it comes into contact with the user as will be explained below. In path **44** a small amount of air penetrates a seal that seals off a hood compartment to further, residually reach the wearer. To prevent atmospheric air from contacting the user and air exhaled by the user from filling the compartments, passage of air between the compartments is controlled by a series of seals and unidirectional valves, as will be described below. Atmospheric air **40** passes through filter **46** and then into manifold **48**. From the manifold **48**, the airflow partitions into either the mouth - nose compartment **50** through a unidirectional valve, or the face compartment **52** through a unidirectional valve, the proportion of airflow into each compartment can be regulated or preset. After flushing the face compartment **52**, air passes through a directional valve, to the mouth - nose compartment **50**. From the mouth - nose compartment **50** the air is emitted to the ambient atmosphere through directional valve. In path **44**, a seal, typically closing on the neck, almost totally prevents penetration of atmospheric air **40** into the hood compartment **54**. Another seal almost totally prevents passage of air from the hood compartment **54** to face compartment **52**. A seal almost totally prevents passage of air from the mouth - nose compartment **50** to the face compartment **52** and vice versa.

To prevent ambient atmospheric air from contacting the user and air exhaled by the user from filling the compartments, passage of air between the compartments is controlled by a series of seals and unidirectional valves, as will be described below. **Fig. 2** is a block diagram describing the topology of the restrictive elements of air - movement employed in a device of the invention: seals and unidirectional valves. Air from the face compartment **52** is driven through unidirectional valve **62** to mouth - nose compartment **50** also receives air directly from air filter **46** through valve **49**. From mouth - nose compartment **50** the air is driven through unidirectional valve **64** to the ambient atmosphere **40**. The face compartment **52** receives air from air filter **46** through valve **66**. The mouth - nose compartment **50** Residual amounts of air are transferred across seal **70**. Hood compartment **54** also interacts with the ambient atmosphere through seal **72**.

A mask in accordance with the present invention provides protection against gasses and aerosols containing chemical and or biological hazardous agents. The novel structure minimizes the occurrence of re-breathing of the exhaled CO_2 - rich and O_2 - poor air by the user. **Fig. 3** describes schematically a side view of a device of the invention and its major components. Hood **90**, covers the head of the wearer and is sealed by a neck seal **72** and at the front of the head by seal **70**. Visor **112** connects to seal **70** and to mouth - nose compartment **50**. The mouth - nose compartment has a rim **114** that typically fits snugly around the bridge of the nose, its sides, the cheek bones, the cheeks and the chin. The rim forms a seal and minimizes air interchange with the face compartment **52**. The mouth - nose compartment **50** preferably has a minimal volume in order to minimize the volume of exhaled air lingering inside the compartment. The wall **116** of the mouth - nose compartment is in a preferred embodiment of the invention made from a semi - rigid material such as silicon. The front wall of the mouth - nose compartment **50** is sufficiently flexible to permit some measure of flexibility for better fit and comfort. The mouth - nose compartment **50** contains several air passageways as will be explained later on. The hood

compartment consists of a complete cover of the head typically made from impermeable flexible material. In a preferred embodiment of the invention, a set of straps **118** keeps the mouth – nose compartment tightly held against the skin. The straps are preferably attached to the sides and top of the hood.

5 The straps are guided through a channel or loop to prevent tangling and facilitate their tightening around the head. In a preferred embodiment of the invention the straps are attached to an anchoring strip on the external surface of the hood **90**. The anchoring strip is connected internally to elastic straps **118** that connect to the rim **70** and to the rim of mouth - nose compartment

10 **114**. Thus, pulling the external straps **140** pulls the face compartment and the mouth - nose compartment tighter to the skin of the face.

In **Fig. 4** the portion of a mask is shown, indicating the air passageways of the device of the invention. The exhalation passageway **210** permits ridding of the exhaled gas. The primary inhalation passageway **212**

15 connects between the manifold **214** and the mouth - nose compartment **50**. In addition, one or more air passageways **216** connect between the face compartment **52** and the mouth -nose compartment **50**. Air passageway **218** also implements a direct connection between these two compartments. Air may thus enter the mouth - nose compartment either directly from the filter **46**

20 via the manifold **214** or indirectly from the filter and manifold through the inner cavity of the face compartment **52**. This partitioning of incoming air facilitates intake of mostly fresh air, with a concomitant flushing the interior of the face compartment to prevent fogging of the visor **112** or build up of CO₂ if there is a leak under the seal of the mouth -nose compartment.

25 The seals of the mouth - nose compartment and the face compartment consist of a semi-rigid outer wall that forms an airtight seal with the skin. This is accomplished through a contoured rim, gas filled cushion, liquid filled cushion or a jell filled cushion, without barring the motion of the mandible for speech and drinking. A detailed description of the airflow inside the facial

30 portions of the device of the invention is provided in **Fig.5** to which reference is now made. Purified air flows in the direction of arrow **310** from the air filter. Air then flows in two passageways, one indicated by arrow **312** to the mouth -

nose compartment, and in parallel as indicated by arrow 314 to the face compartment. In the face compartment, the air flows in the direction of arrows 316 until it enters the mouth – nose compartment as indicated by arrow 318. In its way, the air flows past the visor and diminishes fogging and condensation. Finally air exited through a passageway in the direction of arrow 320.

CLAIMS

- 5 1. A passive system for protecting the respiratory system of a user in which incoming atmospheric air is filtered prior to contacting the user and wherein contact with non filtered atmospheric air by the user is repressed, said system comprising:
- a manifold for supplying filtered air to a mouth – nose compartment and to a face compartment;
 - 10 • an air passageway for passing air from the face compartment to said mouth – nose compartment;
 - an air passageway for letting out air from said mouth – nose compartment into the ambient atmosphere;
 - a hood compartment continuous with the rim of said face compartment and having an air – tight seal with the face at its anterior rim;
 - 15 • an air – tight seal of said hood compartment with the neck of said user,
- and wherein said air passageways are comprise a unidirectional valve.
- 20
2. A passive system for protecting the respiratory system of a user as in claim 1 and wherein the contact of said mouth – nose compartment with the skin is air – tight.
- 25 3. A passive system for protecting the respiratory system of a user as in claim 1 and wherein said mouth – nose compartment is strapped to adjustably strengthen the seal with the face.

4. A method for supplying filtered atmospheric air passively to the face and to the respiratory system, comprising:

- partitioning incoming filtered air to a face compartment and to mouth – nose compartment;
- flushing said face compartment by said incoming air;
- passing air to said mouth – nose compartment, and
- letting used air out of said mouth – nose compartment into the atmosphere.

10

5. A method for supplying filtered atmospheric air passively to the face and to the respiratory system as in claim 4 further comprising restricting entrance of air from a hood compartment to said face compartment.

15

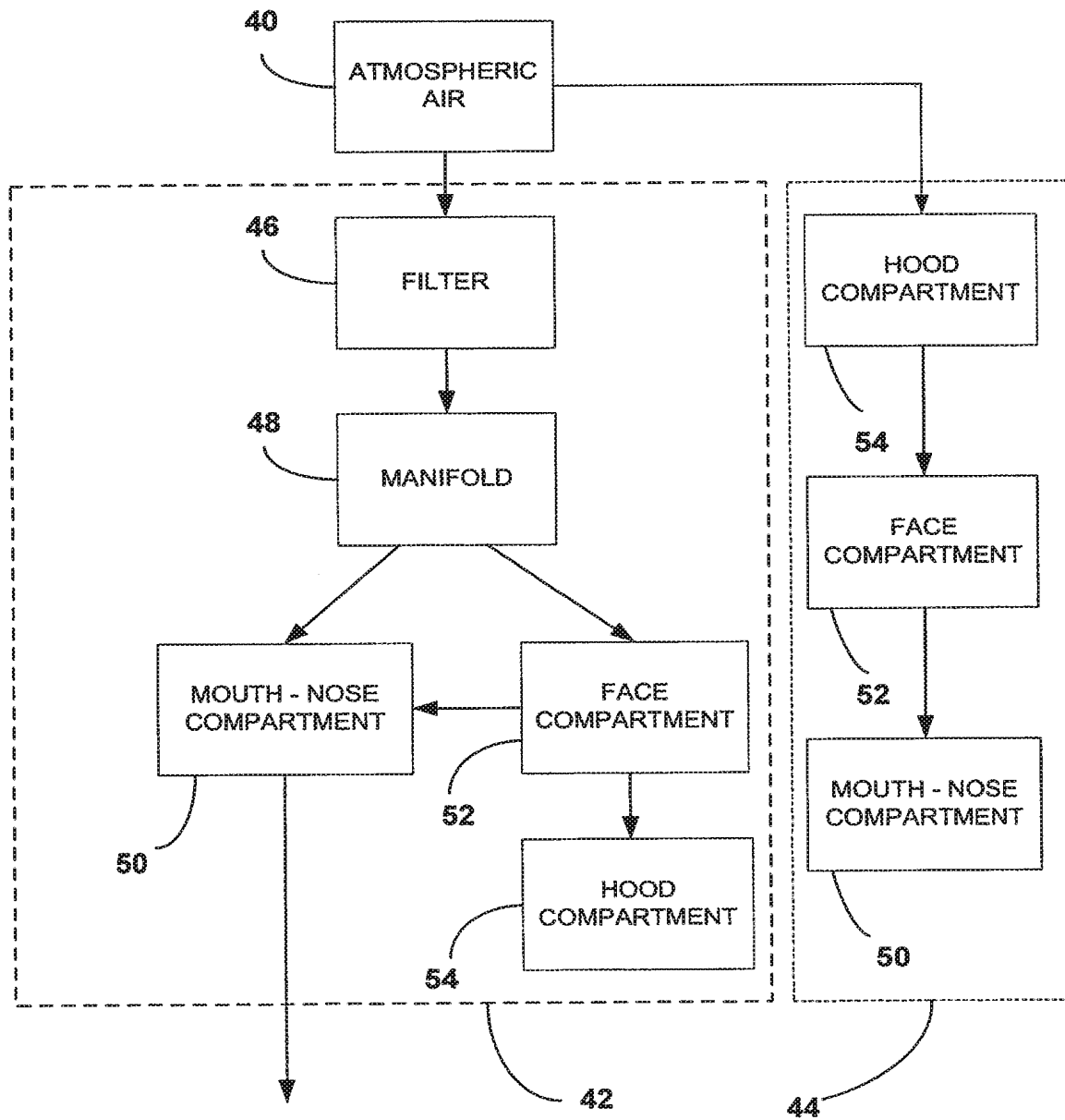


Fig. 1

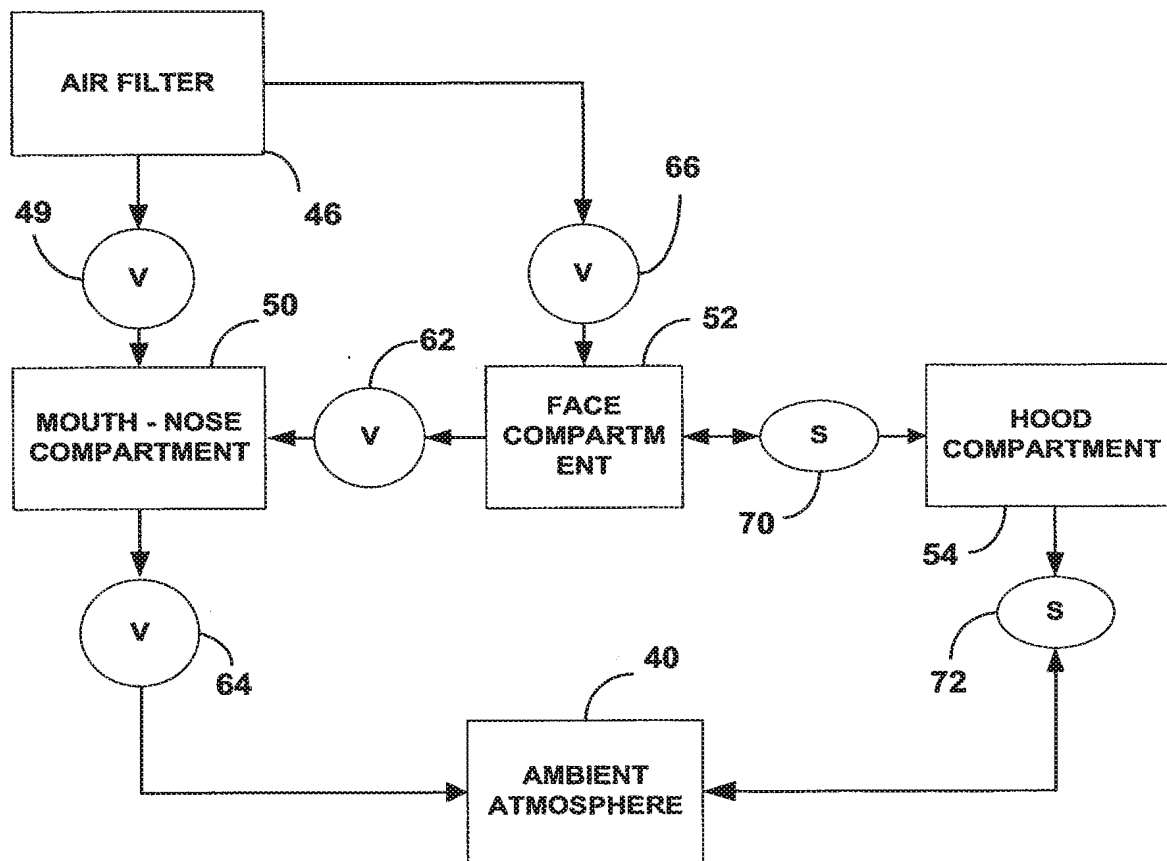


Fig. 2

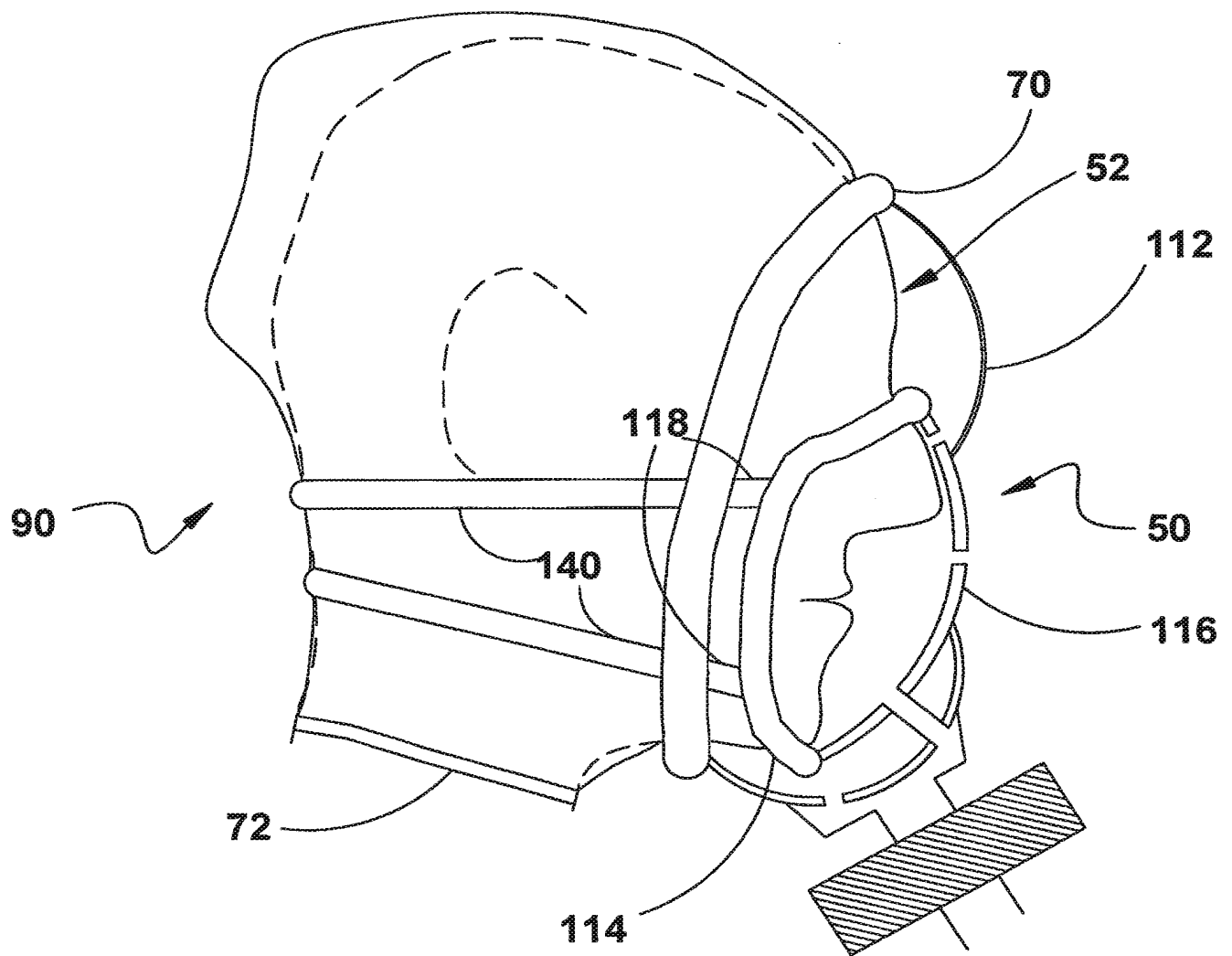


Fig. 3

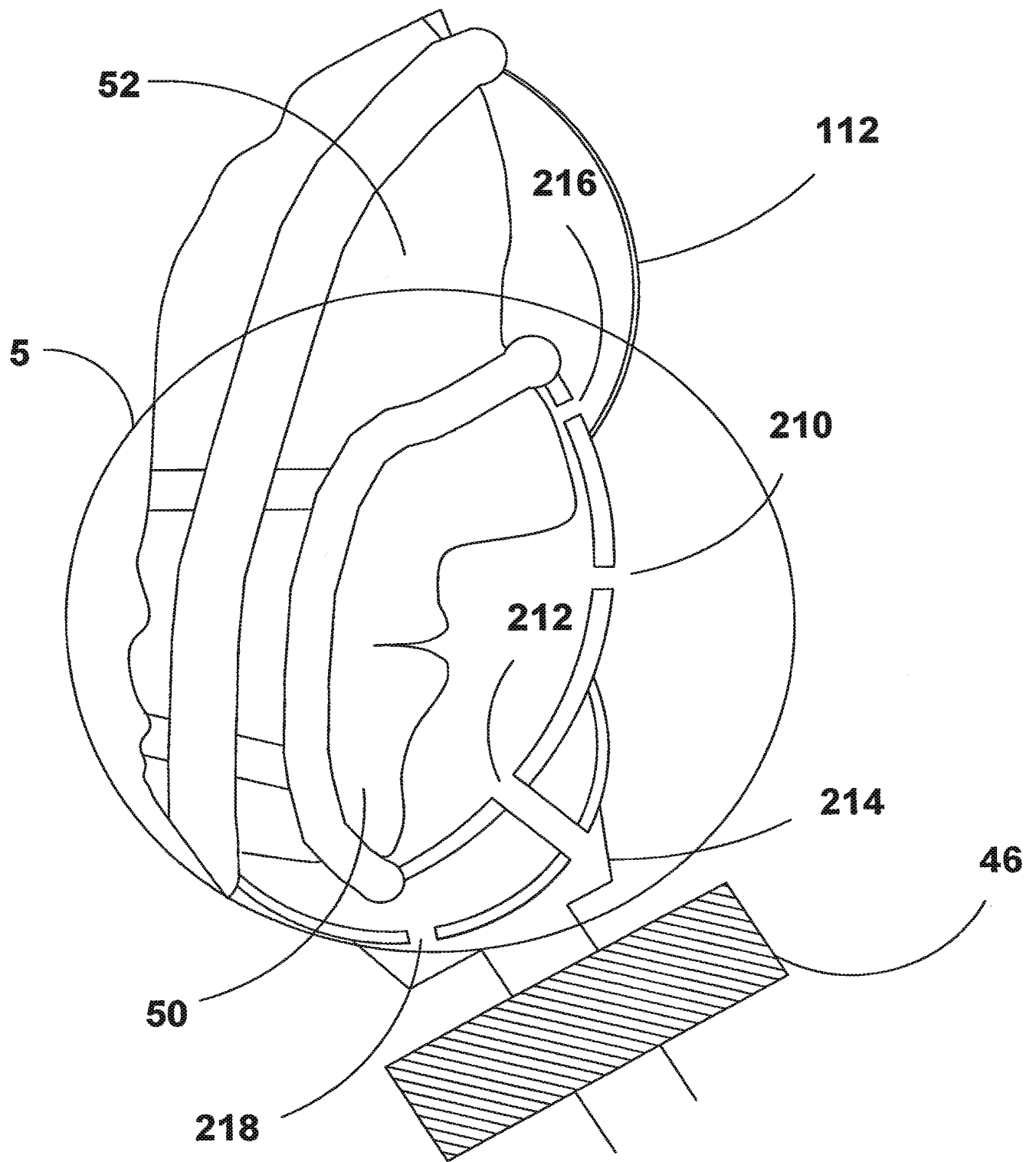


Fig. 4

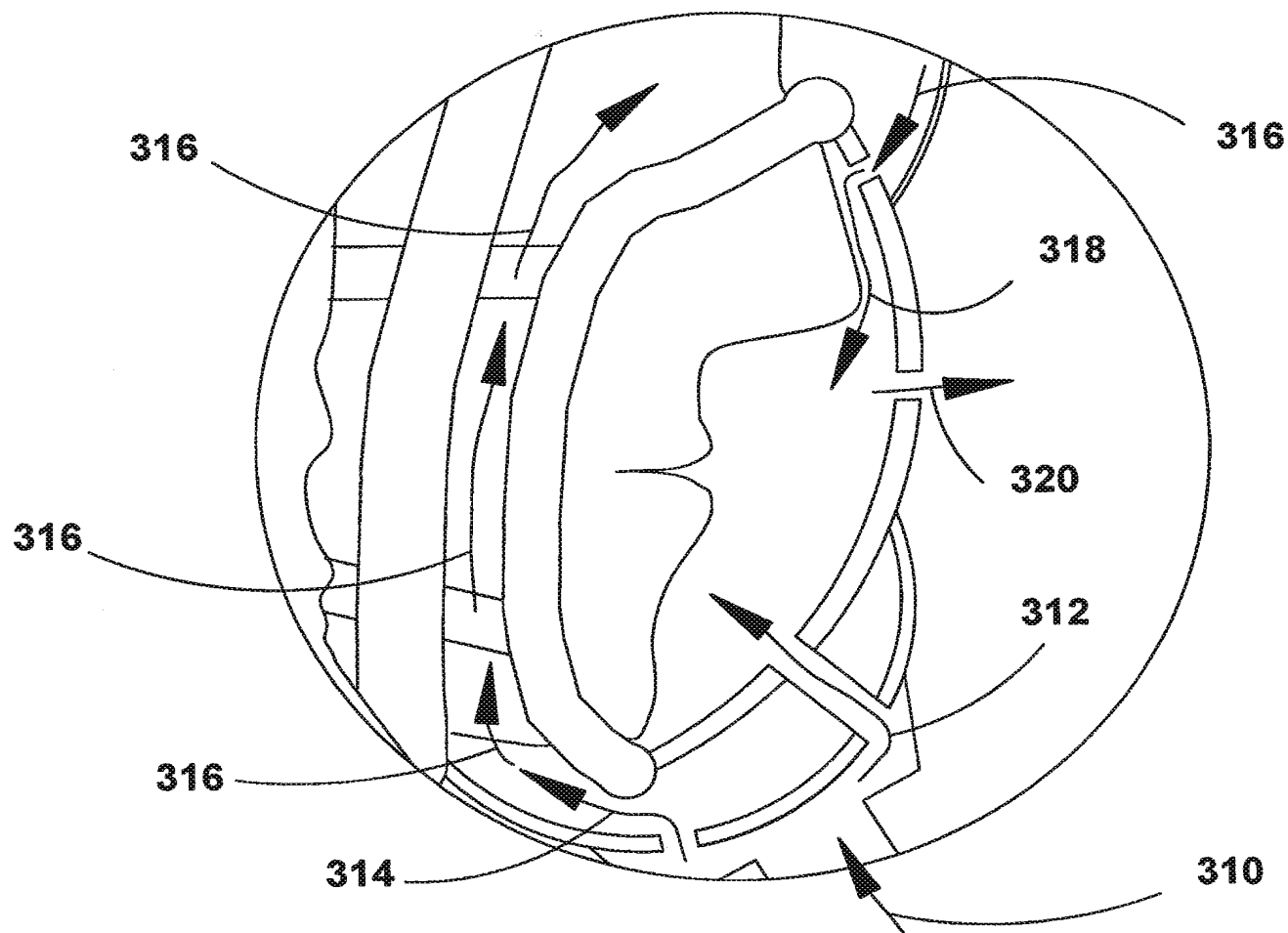


Fig. 5